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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,418	04/26/2006	Shirou Sawa	2006_0177A	7556

513 7590 03/05/2008

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,418	SAWA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *5-9 and 12-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 12-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in the reply filed on January 9, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Application

2. Applicant has elected Group I in response to restriction requirement and elected for the organic amine, the aminoalkylsulfonic acid species with the aminoethylsulfonic acid as the specific species in the group for the examination.

Due to restriction, based on election of Group I, claims 12-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Due to restriction, based on election of aminoalkylsulfonic acid for the organic amine, claims 5-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claims 1-4 and 10-11 are present for examination at this time.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 4, 10-11are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are drawn to the octanol-water partition coefficient of 0.7 to 4 for 2-amino-3-(4-bromobenzoyl) phenylacetic acid (bromfenac) or its pharmacologically acceptable salt or a hydrate thereof comprising an organic amine or a salt thereof in a aqueous eye drop. There is inadequate written description for this phrase. The octanol-water partition coefficient of a compound is a measure of differential solubility of ionized and non-ionized forms in two solvents that can be affected by several things such as pH, solvent, composition of the materials in the solution (e.g. surfactants, chelators), the components themselves, and the amounts present.

The specification discloses that the coefficient of bromfenac is affected by not only the choice of amine, but its concentration. The range of concentrations to attain the range varies dependent on the amine and the comparative for Table 6 shows variation of the amine but as there is no context such as pH or polymers or other components present which would widely affect the coefficient, it is inadequate to show a consistent measure without disclosure to all the components and conditions present at the time of measurement. Additionally, while the specification discloses that the lower ranges of amines in the claims to result in the coefficients without written context, Table 6 shows several amines at concentration of 0.1% 0.5% and 1.0%, it does not show

concentrations of 0.05 to 0.1% for the amines to support the coefficient of 0.7-4. The specification does not provide adequate description for what the conditions and components present in the composition being delivered in the method, indicating that the artisan was not in possession of the claimed invention. As a result, the limitations of what is present in the composition such as the percent concentrations, for delivery for treating inflammation will meet the intended use and coefficient recitations, as it would be expected that the two compositions with the same components in the same concentration ranges will have the same properties, as written in the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 are rejected under 35 U.S.C. 102(XX) as being anticipated by Ogawa et al (U.S. Pat. No. 4910225).

Ogawa teaches a method of treating inflammatory eye disease with an ophthalmic composition comprised of a benzoylphenylacetic acid or its salt or the hydrate, in one or more compound mixtures, buffers, and optionally with an isotonizing agent, a microbiocidal agent, a preservative, a chelating agent, and a thickening agent . The concentration of the active ingredient may range from about 0.001% to about 10%, preferably in the range of 0.01 to about 5%. Ogawa teaches the composition to be

useful in treating inflammatory ophthalmic conditions such as uveitis and conjunctivitis. The composition can be administered in the form of eye drops, ointments and any other known compositions for topical administration to the eye. The eye drops are to be administered one to several drops per dose in a frequency of once to four times a day according to the clinical condition. The dosage may be adjusted according to symptoms.

The specific drug utilized is sodium 3-(4-bromobenzoyl) 2-aminophenylacetate/monohydrate at 0.1% with sodium edentate (EDTA), an organic amine. The recitation of bromfenac to be in the humor for at least 24 hours is a recitation of intended effect which does not have patentable weight as the only component present is bromfenac in claim 1. The limitations to be met are the administration of the composition and its components to the eye for treating inflammation (Abstract, Col. 1, lines 33-38, 60-68, Col. 2, lines 1-36, 45-68, Col. 3, lines 30-54, Col. 4, lines 20-68, Col.5, lines 1-15-23, Col.6, lines 20-48, 53-68, Col.7, lines 1-68, Col8, lines 1-20, 25-68, Col.9, Example 1-2, Col.10, Example 6-7).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al (U.S. Pat. No. 4910225) as applied to claims 1-4 above, in view of XXXX.

The teachings of Ogawa et al. are addressed above.

Owaga et al. does not expressly teach the incorporation of taurine (aminoethylsulfonic acid).

Kato et al. teaches that taurine is effective in the treatment of dry eye, an inflammatory condition. Kato teaches that taurine when delivered to the eye is effective in the range of 0.5 to 3.0% by weight for the treatment of dry eye. When in an amount less that 0.5%wt. the treating effect on dry eye is weak, and when there is more than 3%wt., irritation to the eye occurs due to hypertonia (Col. 1, lines 10-48).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate taurine, as suggested by Kato et al., and produce the instant invention. It would have been obvious to one of skill in the art because taurine is known to be effective in suppressing the release of histamine which is the cascade resulting in inflammation (see Endo et al., Mechanisms…) and has been previously used in ophthalmic solutions (see Huth, U.S. Pat. Pub. No. 2004/0120916 for a summary). It is also naturally found in the eye as an amino acid found typically in the retina.

One of ordinary skill in the art would have been motivated to do this as it is routine in the art to have combine of drugs for the same purpose to provide a more

effective composition to treat the condition desired. Owaga teaches explicitly, the incorporation of other active agents (Col. 4, lines 16-20).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. Claims 1-4 and 10-11 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

/Zohreh A Fay/
Primary Examiner, Art Unit 1612